NOSB ITEM FOR PUBLIC COMMENT

The National Organic Standards Board (NOSB) is seeking public comment on recommendations regarding the continued use of certain nonsynthetic substances in organic handling operations. The public comment period ends on April 10, 2006. With respect to receipt of comments by the NOSB during the comment period, the following provisions have been established to ensure that your comment has the greatest probability of being received and reviewed by the Board:

- **Mail:** Persons may submit comments on listed Board recommendations by mail to: The National Organic Standards Board; c/o Katherine Benham; Room 4008 - South Building; 1400 and Independence Avenue, SW; Washington, D.C. 20250-0001.

- **E-mail:** Comments may be sent via internet to Katherine.Benham@usda.gov.

- **Fax:** Comments may be submitted by fax to (202) 205-7808.

Clearly indicate if you are for or against the Board recommendation or some part of it and why. Include recommended wording changes as appropriate. Include a copy of articles or other references that support your comments. Only relevant material should be submitted.

Handling Committee Draft Recommendation
February 1, 2006

I. List: 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food groups."

(a) Nonsynthetics allowed

II. Committee Summary:

There were many comments recommending the continued allowance of non-synthetic colors and flavors in organic handling. The federal register notice regarding Sunset Review asked the public to provide evidence and address concerns for any substance they believed should be discontinued. There were no specific comments against the continuation of either colors or flavors on the National List.

There was a comment addressing the concern that colors and flavors were added to the National List without a technical review by the NOSB. The Handling Committee requested and received a technical overview of food color additives and flavors on October 14, 2005. This technical review offered no information that would suggest that either non-synthetic colors or flavors are inconsistent with organic practices.

The use of flavoring substances is regulated by the FDA. All flavoring substances, non-synthetic, fall into one of two categories. They are either GRAS (Generally Recognized As Safe) a designation granted by a panel of technical experts whose authority is accepted by the FDA, or they are food additives that have been reviewed and approved by the FDA directly. Currently, there are no GRAS exemptions for color additives. To obtain approval from the FDA for a color or flavor as a food additive, the manufacturer must submit a petition demonstrating safety of the substance with information including manufacturing process, stability data, safety studies and toxicity data. Consequently, all non-synthetic flavoring substances and colors are subject to premarket approval requirements.

III. Committee Recommendation(s):

The handling committee recommends the renewal of the following substances in this use category as published in the final rule:

Colors, nonsynthetics sources only
Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

Moved: Kevin O'Rell Second: Joe Smillie
Committee vote: Yes: 5 No: 0 Abstain: 0

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO OR REMOVED FROM THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?
Substance __Colors_____

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]				In filing a color additive petition, the manufacturer is responsible for providing FDA with information re manufacturing process description. From "Overview of Food Color Additives 10-14-05. Colors are categorized either as "certifiable (those derived from petroleum and known coal-tar dyes) or "exempt from certification" (those obtained largely from mineral, plant or animal sources). There are a broad group of exempt color additives and more information would be needed to address this question.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]				In filing a color additive petition, the manufacturer is responsible for providing FDA with information re manufacturing process description. From "Overview of Food Color Additives 10-14-05. Colors are categorized either as "certifiable (those derived from petroleum and known coal-tar dyes) or "exempt from certification" (those obtained largely from mineral, plant or animal sources). There are a broad group of exempt color additives and more information would be needed to address this question.
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		XX		In filing a color additive petition, the manufacturer is responsible for providing FDA with information regarding stability and inherent toxicity studies. From "Overview of Food Color Additives 10-14-05.
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]				
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		XX		In filing a color additive petition, the manufacturer is responsible for providing FDA with information regarding stability studies and physical, chemical and biological properties. From "Overview of Food Color Additives 10-14-05.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			XX	This substance is intended for food application.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			XX	This substance is intended for food application.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		XX		In filing a color additive petition, the manufacturer is responsible for providing FDA with information regarding stability and inherent toxicity studies. From "Overview of Food Color Additives 10-14-05.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]			XX	This substance is intended for food application.
10. Is there any harmful effect on human health?				To obtain approval from the FDA for a new color additive, the manufacturer must submit a petition

[§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]	XX			demonstrating the safety and suitability of the new color additive or new use. FDA is then responsible for evaluating the petition and determining whether the color additive is safe for human consumption. With this regulatory process, color additives generally have a good safety record; however some adverse reactions have been noted. FDA's safety assessment includes a review of toxicity data such as the results of controlled animal studies. From "Overview of Food Color Additives 10-14-05.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]	XX			With this regulatory process, color additives generally have a good safety record; however some adverse reactions have been noted. From "Overview of Food Color Additives 10-14-05.
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]		XX		Currently there are no GRAS exemptions for color additives. Consequently, all color additives are subject to premarket approval requirements. From "Overview of Food Color Additives 10-14-05.
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		XX		In filing a color additive petition, the manufacturer is responsible for providing FDA with information regarding chemical specifications. From "Overview of Food Color Additives 10-14-05.

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 2. Is the Substance Essential for Organic Production?

Substance _____

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]				Colors are a broad category of color additives. Specific information on formulation or manufacturing process is not available for all colors that are "exempt from certification" (that is those colors obtained largely from mineral, plant or animal sources). More information is needed.
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]				Colors are a broad category of color additives. Specific information on formulation or manufacturing process is not available for all colors that are "exempt from certification" (that is those colors obtained largely from mineral, plant or animal sources). More information is needed.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]				Colors are a broad category of color additives. Specific information on formulation or manufacturing process is not available for all colors that are "exempt from certification" (that is those colors obtained largely from mineral, plant or animal sources
4. Is there a natural source of the substance? [§205.600 b.1]	XX			There are natural sources (plant) of certain colors available.
5. Is there an organic substitute? [§205.600 b.1]	XX			There are some organic vegetable extracts that are used as colorants, i.e. organic beet root juice. Possibly not all color applications would be available in organic form. More information is needed.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	XX			Colors were included among the substances initially placed on the National List when the USDA promulgated regulations pursuant to the OFPA of 1990. Today there are many organic products that contain organic compliant colors.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	XX			There are natural sources of certain colors available that are extracted from plant material.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	XX			There are colors used in organic products that are not synthetic but not organically produced.
9. Is there any alternative substances? [§6518 m.6]			XX	
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	XX			Products could be produced without the use of color additives, but would be less appealing to consumers.

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b)are N/A—not applicable.

Category 3. Is the substance compatible with organic production practices?

Substance _____

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]	XX			Colors were included among the substances initially placed on the National List when the USDA promulgated regulations pursuant to the OFPA of 1990. Today there are many organic products that contain organic compliant colors.
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		XX		Colors can be categorized as "exempt from certification" (those obtained largely from mineral, plant or animal sources). Many of these colors are derived form Agricultural sources.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		XX		Colors can be categorized as "exempt from certification" (those obtained largely from mineral, plant or animal sources). Many of these colors are derived form Agricultural sources.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]		XX		The specific use is to provide color to a food product.
5. Is the primary use as a preservative? [§205.600 b.4]		XX		The specific use is to provide color to a food product.
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]	XX			In some cases colorants are added to enhance the color that could be lost during the process.
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;			XX	This substance is intended for use as a food ingredient.
b. toxins derived from bacteria;			XX	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			XX	
d. livestock parasiticides and medicines?			XX	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			XX	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

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